

K183687 LifeWindow LW8 LiteSep 25, 2019
271 days to decisionK183687 · Product code: **MWI** · Cardiovascular
Source: <https://www.510kdatabase.net/k183687/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI) |
| Date received | Dec 28, 2018 |
| Decision date | Sep 25, 2019 |
| Days to decision | 271 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Digicare Biomedical Technology, Inc. |
| Location | Boynton Beach, FL, US |
| Contact | Eduardo Miranda |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k183687/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026